



IFW

Attorney Docket No. 0341-0030.42

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Application of:

Ron WAKSMAN et al

Serial No.: 10/817,549

Filed: April 4, 2004

Examiner:

Art Unit: 3763

For: METHOD AND APPARATUS FOR TREATING  
A DESIRED AREA IN THE VASCULAR  
SYSTEM OF A PATIENT

)  
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) - Date: September 23, 2004

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97, as revised on February 4, 1992, 1135 OG 23-24, Applicant hereby calls the Examiner's attention to documents listed on the attached form, which documents may be material to the examination of this application. Each of the cited documents is believed to have been cited in one of the parent applications relied upon for priority under 35 USC §120 or a related application. It is not believed that a copy of the references needs to be submitted.

If the Examiner wishes to receive a copy of any of these references, it is respectfully requested that he contact the

undersigned regarding the desired reference and the undersigned will gladly provide the reference.

No inference should be drawn that the attached list sets forth a comprehensive investigation of the prior art, that any or all are pertinent to the invention, or that any apparatus disclosed is equivalent to the subject invention.

The citation of the above-discussed documents is not to be construed as an assertion that more pertinent art could not possibly be in existence. Citation of any document herein is not to be construed as an admission that any subject matter disclosed in the document is necessarily within the inventive field of endeavor, that any disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that any disclosure is otherwise necessarily prior art with respect to the instant invention.

Applicant also respectfully reserves the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosure of those documents discussed herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

Please charge our Deposit Account No. 50/1039 for any fee due for this IDS.

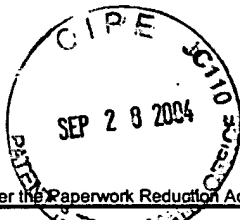
Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Mark J. Murphy", is written over a horizontal line.

Mark J. Murphy

Registration No.: 34,225

COOK, ALEX, McFARRON, MANZO,  
CUMMINGS & MEHLER, LTD.  
200 West Adams Street  
Suite 2850  
Chicago, Illinois 60606  
(312) 236-8500



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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 6

of 14

**Complete if Known**

Application Number	10/817,549
Filing Date	April 2, 2004
First Named Inventor	Ron Waksman et al.
Art Unit	3763
Examiner Name	
Attorney Docket Number	0341-0030.42

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5,503,614	04-02-1996	Liprie	
		US- 5,533,969	07-09-1996	Mulder	
		US- 5,556,389	09-17-1996	Liprie	
		US- 5,575,749	11-19-1996	Liprie	
		US- 5,624,372	04-29-1997	Liprie	
		US- 5,643,171	07-01-1997	Bradshaw, et al.	
		US- 5,713,828	02-03-1998	Coniglione	
		US- 5,807,231	09-15-1998	Liprie	
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		US- 5,851,172	12-22-1998	Bueche, et al.	
		US- 5,857,956	01-12-1999	Liprie	
		US- 5,863,284	01-26-1999	Klein	
		US- 5,899,882	05-04-1999	Waksman, et al.	
		US- 6,013,020	01-11-2000	Meloul, et al.	
		US- 6,074,338	06-13-2000	Popowski, et al.	
		US- 6,306,074	10-23-2001	Waksman, et al.	
		US- 6,458,070	10-01-2002	Waksman, et al.	
		US- 6,503,185	01-07-2003	Waksman, et al.	
		US- 6,514,193	02-04-2003	Kaplan	

**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

Examiner  
Signature

Date

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

***(Use as many sheets as necessary)***

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Application Number	10/817,549
Filing Date	April 2, 2004
First Named Inventor	Ron Waksman et al.
Art Unit	3763
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Attorney Docket Number	0341-0030.42

Sheet	7	of	14
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## U. S. PATENT DOCUMENTS

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Sheet 8	of 14	Attorney Docket Number	0341-0030.42

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	NISAR SYED A.M., FEDER B., "Technique of After-Loading Interstitial Implants", Syed/Feder, Radiologia Clinica 46:458-476 (1977).	
	2	NISAR SYED et al., "Combination of External and Interstitial Irradiation in the Primary Management of Breast Carcinoma", CANCER vol. 46, No. 6, pp. 1360-1365 (1980).	
	3	PUTHAWALA et al., "Temporary Iridium 192 Implant in the Management of Carcinoma of the Prostate", ENDOCURIETHERAPY/HYPERTHERMIA ONCOLOGY 1:25-34 (1985).	
	4	NISAR SYED et al., "Transperineal Interstitial-Intracavitary "Syed-Neblett" Applicator in the Treatment of Carcinoma of the Uterine Cervix", ENDOCURIETHERAPY/HYPERTHERMIA ONC-	
		LOGY 2:1-13 (1985).	
	5	NISAR SYED A.M. et al., "Intraluminal Irradiation in the Treatment of Esophageal Cancer", ENDOCURIETHERAPY/HYPERTHERMIA ONCOLOGY 3:105-113 (1987).	
	6	FAXON et al., "Mechanism of Angioplasty and Its Relation to Restenosis", AMERICAN JOURNAL OF CARDIOLOGY 15:5B-9B (1987).	
	7	BOROK et al. "Rule of Ionizing Irradiation for 393 Keloids", I.J. RADIATION ONCOLOGY-BIOLOGY-PHYSICS 17:77-80 (1989).	
	8	KOVALIC/PEREZ, "Radiation Therapy Following Keloidectomy: A 20-Year Experience", I.J. RADIATION ONCOLOGY-BIOLOGY-PHYSICS 17:77-80 (1989).	
	9	MCCORMICK et al., "Breast Cancer", Chpt. 25 of INTERSTITIAL BRACHYTHERAPY 221-226 (1990).	

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	10	DAWSON, "Theoretic Considerations Regarding Low-Dose Radiation Therapy for Prevention of Restenosis after Angioplasty", THE READING HOSPITAL & MEDICAL CENTER 18(1) 4-7 (1991).	
	11	Skin, p. 261 of the American Medical Association Family Medical Guide, Editor Kunz.	
	12	Endovascular Low-Dose Irradiation Inhibits Neointima Formation after Coronary Artery Balloon Injury in Swine - A Possible Role for Radiation Therapy in Restenosis Prevention,	
		by Ron WAKSMAN, MD; Keith A. ROBINSON, PhD; Ian R. CROCKER, MD; Michael B. GRAVANIS, MD; Gustavo D. CIPOLLA, DVM; Spencer B. KING III, MD, CIRCULATION vol. 91, No. 5, pp. 1533	
		-1539 (Mar. 1, 1995). Submitted for publication Oct. 3, 1994.	
	13	Endovascular Low-Dose Irradiation Inhibits Neointima Formation after Coronary Artery Balloon Injury in Swine - A Possible Role for Radiation Therapy in Restenosis Prevention,	
		by Ron WAKSMAN, MD; Keith A. ROBINSON, PhD; Ian R. CROCKER, MD; Gustavo D. CIPOLLA, DVM; Spencer B. KING III, MD. Submitted for publication Mar. 25, 1994.	
	14	SCHWARTZ et al., "Effect of External Beam Irradiation on Neointimal Hyperplasia after Experimental Coronary Artery Injury", American College of Cardiology, JACC vol. 19,	
		No. 5, (Apr. 1992), pp. 1106-1113.	
	15	STEIDLE, B., "Preventative Percutaneous Radiation Therapy to Avoid Hyperplasia of the Intima after Angioplasty Combined with Stent Implantation", STRAHLENTHER ONKOL, (1994),	

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		170:151-154.	
	16	WIEDERMANN et al., "Effects of High-Dose Intracoronary Irradiation on Vasomotor Function and Smooth Muscle Histopathology", AMERICAN PHYSIOLOGICAL SOCIETY, (1994), pp. H125-	
		H132.	
	17	ABBAS et al., "External Beam Irradiation Inhibits Neointimal Hyperplasia Following Balloon Angioplasty", INTERNATIONAL JOURNAL OF CARDIOLOGY, 44 (1994), 191-202.	
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	20	WIEDERMANN et al., "Intracoronary Irradiation Markedly Reduces Restenosis after Balloon Angioplasty in a Porcine Model", American College of Cardiology, JACC, vol. 23, No. 6,	
		pp. 1491-1498 (May 1994).	
	21	FISCHELL et al., "Low-Dose, Beta-Particle Emission from 'Stent' Wire Results in Complete, Localized Inhibition of Smooth Muscle Cell Proliferation", BASIC SCIENCE REPORTS,	

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Sheet 11	of 14	Attorney Docket Number	0341-0030.42

NON PATENT LITERATURE DOCUMENTS			
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		Circulation, vol. 90, No. 6, (Dec. 1994), pp. 2956-2963.	
	22	FRIEDMAN, "Pathogenesis of the Spontaneous Atherosclerotic Plaque", ARCHIVES OF PATHOLOGY, vol. 76, (Sept. 1963), 94-105.	
	23	FRIEDMAN et al., "Cortisone and Experimental Atherosclerosis", ARCHIVES OF PATHOLOGY, vol. 77, (Feb. 1964), 56-72.	
	24	FRIEDMAN et al., "Aortic Atherosclerosis Intensification in Rabbits by Prior Endothelial Denudation", ARCHIVES OF PATHOLOGY, vol. 79, (Apr. 1965), 345-356.	
	25	FRIEDMAN and BYERS, "Effect of Iridium 192 Radiation on Thromboatherosclerotic Plaque in the Rabbit Aorta", ARCHIVES OF PATHOLOGY, vol. 80, (Sep. 1965).	
	26	FRIEDMAN, FELTON, and BYERS, "The Antiatherogenic Effect of Iridium 192 upon the Cholesterol-fed Rabbit", Journal OF CLINICAL INVESTIGATION, vol. 43, No. 2, (1964), 185-192.	
	27	HILARIS, B.S., et al., ATLAS OF BRACHYTHERAPY Chapter 2, "Brachytherapy Instruments", title & cover pages, p. 28, pp. 42-43, (1988).	
	28	MELKERT, R., et al., "Luminal Narrowing after Percutaneous Transluminal Coronary Angioplasty. A Multivariate Analysis of Clinical, Procedural and Lesion Related Factors Affecting Long-term Angiographic Outcome in the PARK Study", J. INVASIVE CARDIOLOGY, vol. 6, No. 5, pp. 160-171 (Jun. 1994).	
	29	FISHMAN, D., et al., Abstract: "A Randomized Comparison of Coronary-stent Placement and Balloon Angioplasty in the Treatment of Coronary Artery Disease", NEW ENGLAND J. OF	

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		MEDICINE, p. 496 (Aug. 25, 1994).	
	30	NICOLINI, F., et al., "Biology of Restenosis and Therapeutic Approach", ENDOVASCULAR SURGERY, vol. 72, No. 4, pp. 919-935 (Aug. 1992).	
	31	WEIDERMANN, J., et al., Abstract: "Intracoronary Irradiation Acutely Impairs Endothelial and Smooth Muscle Function as Assessed by Intravascular Ultrasound", Supplement to	
		CIRCULATION, vol. 86, No. 4, p. I-188, Abstract No. 0750 (Oct. 1992).	
	32	LANDAU, C., et al., "Percutaneous Transluminal Coronary Angioplasty", NEW ENGLAND J. OF MED., vol. 3330, No. 14, pp. 981-983 (Apr. 7, 1994).	
	33	PARANANDI, S., et al., "Contemporary Clinical Trials of Restenosis", J. OF INVASIVE CARDIOLOGY, vol. 6, No. 4, pp. 109-123 (May 1994).	
	34	WIEDERMANN et al., "Intracoronary Irradiation Markedly Reduces Restenosis after Balloon Angioplasty in a Porcine Model", JACC, vol. 23, No. 6, pp. 1491-1498 (May 1994).	
	35	GLAGOV, S., "Intimal Hyperplasia, Vascular Modeling, and the Restenosis Problem", CIRCULATION, vol. 89, No. 6, pp. 2888-2891 (Jun. 1994).	
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		RADIATION ONCOLOGY, BIOLOGY, PHYSICS, vol. 29, (Nov. 1994), 183-186.	

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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	10/817,549
		Filing Date	April 2, 2004
		First Named Inventor	Ron Waksman et al.
		Art Unit	3763
		Examiner Name	
Sheet 13	of 14	Attorney Docket Number	0341-0030.42

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	37	LIERMANN et al. "Prophylactic Endovascular Radiotherapy to Prevent Intimal Hyperplasia after Stent Implantation in Femoropopliteal Arteries", CARDIOVASCULAR AND INTERVENTIONAL RADIOLOGY, (1994), 17:12-16.	
	38	Supplementary European Search Report - EP 97 92 2288.	
	39	Annex to the European Search Report on European Patent Application No. EP 97 92 2288.	
	40	HERRMAN, J., et al., "Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty", DRUGS, 46(1): pp. 18-52 (1993).	
	41	LANGE, R., et al., "Southwestern Internal Medicine Conference: Restenosis: The Achilles Heel of Coronary Angioplasty", AMER. J. OF THE MEDICAL SCIENCES, vol. 306, pp. 265-273 (Oct. 1993)	
	42	MYLER, R., et al., "Restenosis after Coronary Angioplasty: Pathophysiology and Therapeutic Implications (Part 1 of Two Parts), J. OF INVASIVE CARDIOLOGY, vol. 5, No. 8, pp. 278-285, (Oct. 1993).	
	43	WEIDERMANN, J., et al., Abstract: "Intracoronary Irradiation Markedly Reduces Restenosis after Balloon Angioplasty in a Porcine Model", Supplement of CIRCULATION, vol. 88,	

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